IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; and GILEAD SCIENCES, INC. Plaintiffs, v. ACCORD HEALTHCARE, INC., Defendant.	C.A. No. 1:19-cv-1199-CFC

DEFENDANT ACCORD HEALTHCARE, INC.'S ANSWER AND DEFENSES TO COMPLAINT

Defendant Accord Healthcare, Inc., ("Accord"), by its attorneys, hereby responds to the allegations set forth in the Complaint for Patent Infringement filed by Plaintiffs Astellas US LLC and Astellas Pharma US, Inc. (collectively, "Astellas") and Gilead Sciences, Inc. ("Gilead") (Astellas and Gilead, collectively, "Plaintiffs"):

RESPONSES TO ALLEGATIONS PERTAINING TO THE NATURE OF THE ACTION

> 1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Accord Healthcare, Inc. ("Accord"). This action relates to Abbreviated New Drug Application ("ANDA") No. 213236 filed by Accord with the U.S. Food and Drug Administration ("FDA").

RESPONSE: Accord admit the Complaint purports to set forth an action for patent infringement under Title 35, United States Code, Against Accord, ostensibly in connection with Accord's filing of ANDA No. 213236. Accord denies all remaining allegations. Allegations not expressly

admitted are denied.

> 2. In ANDA No. 213236, Accord seeks approval to market 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson, a generic version of Plaintiffs' Lexiscan® drug product (the "Accord ANDA product"), prior to expiration of U.S. Patent Nos. 8,106,183 (the "'183 patent"), RE 47,301 (the "'301 patent"), and 8,524,883 (the "'883 patent"). The '183 patent, '301 patent, and '883 patent are collectively referred to herein as the "patents-in-suit."

RESPONSE: Accord admits ANDA No. 213236 seeks regulatory approval of 0.4 mg/5 ml (0.08 mg/ml) intravenous solution of regadenoson, which is bioequivalent to the drug product marketed as Lexiscan, prior to expiration of the '183, '301 and '883 patents but denies that ANDA No. 213236 addresses the '883 patent. Accord denies any remaining allegations. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO THE PARTIES

> 3. Astellas US LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062.

RESPONSE: Accord is without information sufficient to form a belief as to the truth of the allegations and denies them on that basis.

> 4. Astellas Pharma US, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062.

RESPONSE: Accord is without information sufficient to form a belief as to the truth of the allegations and denies them on that basis.

> 5. Gilead is a corporation organized and existing under the laws of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, CA 94404.

RESPONSE: Accord is without information sufficient to form a belief as to the truth of the

allegations and denies them on that basis.

> 6. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including diagnostic pharmacologic stress agents. Plaintiffs sell Lexiscan in this judicial district and throughout the United States.

RESPONSE: Accord is without information sufficient to form a belief as to the truth of the allegations and denies them on that basis.

> 7. Upon information and belief, Accord is a corporation organized and existing under the laws of North Carolina, having its principal place of business at 1009 Slater Road, Suite 210b, Durham, North Carolina 27703.

RESPONSE: Accord admits it is incorporated in North Carolina and has a place of business at 1009 Slater Road, Suite 210b, Durham, North Carolina 27703. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

> 8. This case arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over its subject matter under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE: Accord admits Plaintiffs purport to bring this case under the patent laws of the United States. Accord admits the Court has subject matter jurisdiction over this action. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

> 9. This Court has jurisdiction over Accord because, *inter alia*, Accord has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, both Delaware corporations, in Delaware. For example, on information and belief, following approval of ANDA No. 213236, Accord will make, use, import, sell, and/or offer for sale the Accord ANDA Product in the United States, including in Delaware, prior to the expiration of the patents-in-suit.

RESPONSE: Accord denies all allegations; however, in the interest of judicial economy, and solely for the purpose of this litigation, Accord declines to challenge personal jurisdiction.

> 10. This Court also has jurisdiction over Accord because, *inter alia*, this action arises from actions of Accord directed toward Delaware, and because Accord has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Accord regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. Upon information and belief, Accord derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

RESPONSE: Accord denies all allegations; however, in the interest of judicial economy, and solely for the purpose of this litigation, Accord declines to challenge personal jurisdiction.

> 11. Accord has previously consented to suit in this judicial district and has availed itself of Delaware courts through the assertion of counterclaims in suits brought in Delaware including *Millennium Pharmaceuticals, Inc. v. Accord Healthcare, Inc.*, No. 12-1490-GMS, D.I. 10 (D. Del. Jan. 9, 2013); *BioPharma UCB, Inc. v. Accord Healthcare, Inc.,* No. 13-1206-LPS, D.I. 9 (D. Del. Aug. 5, 2013); *Cephalon, Inc. v. Accord Healthcare, Inc. and Intas Pharmaceutical LRD.*, No. 13- 02095-GMS, D.I. 12 (D. Del. April 8, 2014); *Acorda Therapeutics v. Accord Healthcare, Inc.*, No. 1:14-00932-LPS, D.I. 11 (D. Del. Aug. 19, 2014); *Forest Labs., LLC v. Accord Healthcare Inc*., No. 15-272-GMS, D.I. 11 (D. Del. June 1, 2015).

RESPONSE: Accord admits it has previously consented to suit in Delaware in the interest of judicial economy. In that same interest, and solely for the purpose of this litigation, Accord does not challenge personal jurisdiction. All remaining allegations are denied. Allegations not expressly admitted are denied.

> 12. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

RESPONSE: Accord denies venue is proper in this Court; however, in the interest of judicial economy, and solely for the purpose of this litigation, Accord does not

challenge venue.

13. Accord, through its counsel, by e-mail dated June 25, 2019, agreed that it does not contest jurisdiction or venue in this Court in this matter.

RESPONSE: Accord admits that, on or around June 25, 2019, Accord agreed, in the interest of judicial economy, and solely for the purpose of this litigation, it would not challenge jurisdiction or venue. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO THE PATENTS-IN-SUIT

14. On January 31, 2012, the U.S. Patent and Trademark Office duly and legally issued the '183 patent, titled "Process for preparing an A2*A*-adenosine receptor agonist and its polymorphs." A true and correct copy of the '183 patent is attached hereto as Exhibit A. The claims of the '183 patent are valid, enforceable, and not expired. Gilead is the owner of the '183 patent and Astellas US LLC is the exclusive licensee of the '183 patent.

RESPONSE: Accord admits the '183 patent, which is titled "Process for preparing an A2*A*-adenosine receptor agonist and its polymorphs," issued January 31, 2012. Accord denies that the '183 patent was "duly and legally issued." Accord admits that Exhibit A to the complaint appears to be a complete copy of the '183 patent. Accord admits the claims of the '183 patent are not expired. Accord is without information pertaining to the ownership and licensing of the '183 patent sufficient to allow it to form a belief as to the truth of the relevant allegations and denies them on that basis. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

15. On March 19, 2019, the United States Patent and Trademark Office duly and legally issued the '301 patent, titled "Process for preparing an A2*A*-adenosine receptor agonist and its polymorphs." The '301 patent is a reissue of U.S. Patent No. 9,085,601 (the "'601 patent"), which issued on July 21, 2015. A true and correct copy of the

> ’301 patent is attached hereto as Exhibit B. The claims of the ’301 patent are valid, enforceable, and not expired. Gilead is the owner of the ’301 patent and Astellas US LLC is the exclusive licensee of the ’301 patent.

RESPONSE: Accord admits the ’301 patent, which is titled “Process for preparing an A2*A*-adenosine receptor agonist and its polymorphs,” issued March 19, 2019. Accord denies that the ’301 patent was “duly and legally issued.” Accord admits the ’301 patent is a reissuance, in part, of the ’601 patent, which issued July 21, 2015. Accord admits that Exhibit B to the Complaint appears to be an accurate copy of the ’301 patent. Accord admits the claims of the ’301 patent are not expired. Accord is without information pertaining to the ownership and licensing of the ’301 patent sufficient to allow it to form a belief as to the truth of the relevant allegations and denies them on that basis. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

> 16. On September 3, 2013, the United States Patent and Trademark Office duly and legally issued the ’883 patent, titled “Monohydrate of (1-{9-[4S,2R,3R,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]-6-aminopu- rin-2-yl}pyrazol-4-yl)-N-methylcarboxamide.” A true and correct copy of the ’883 patent is attached hereto as Exhibit C. The claims of the ’883 patent are valid, enforceable, and not expired. Gilead is the owner of the ’883 patent and Astellas US LLC is the exclusive licensee of the ’883 patent.

RESPONSE: Accord admits the ’883 patent, which is titled “Monohydrate of (1-{9-[4S,2R,3R,5R)-3,4-dihydroxy-5- (hydroxymethyl)oxolan-2-yl]-6-aminopu- rin-2-yl}pyrazol-4-yl)-N-methylcarboxamide,” issued September 3, 2013. Accord denies that the ’883 patent was “duly and legally issued.” Accord admits that Exhibit C to the Complaint appears to be an accurate copy of the ’883 patent. Accord admits the claims of the ’883 patent are not expired. Accord is without information pertaining to the ownership and licensing of the ’883 patent sufficient to allow it to form a belief as to the truth of the relevant allegations and denies them on that basis. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

17. Astellas Pharma US, Inc. is the holder of New Drug Application ("NDA") No. 022161, by which the FDA granted approval for the marketing and sale of 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson. Plaintiffs market 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson in the United States, under the trade name "Lexiscan®." The FDA's official publication of approved drugs (the "Orange Book") includes Lexiscan together with the '183 and '301 patents. Lexiscan is a pharmacologic agent used in a cardiac nuclear stress test. Lexiscan works by increasing blood flow in the coronary arteries. Lexiscan is given prior to a myocardial perfusion imaging (MPI) test, which provides physicians with detailed information about blood flow into a patient's heart. Approximately half of the people undergoing a cardiac stress test are unable to use a treadmill or a stationary bicycle because of medical conditions. Lexiscan may be used when a person is unable to exercise enough to increase blood flow to the heart during a cardiac nuclear stress test.

RESPONSE: Accord admits the FDA's Orange Book includes the drug marketed as Lexiscan, which identifies the '183 and '301 patents, but not the '883 patent, as covering Lexiscan. Accord is without information sufficient to form a belief as to the truth of the remaining allegations and denies them on that basis. Accord objects to this paragraph as containing allegations that are not relevant to the patents in suit or the claims asserted in the Complaint. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

18. The prescribing information for Lexiscan identifies the drug as "a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress." A copy of the complete prescribing information for Lexiscan approved in NDA No. 022161 is attached as Exhibit D.

RESPONSE: Accord is without information sufficient to allow it to form a belief as to the truth of the allegations and denies them on that basis. Accord objects to this paragraph as containing allegations that are not relevant to the patents in suit or the claims asserted in the Complaint. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

19. The '883 patent claims processes for preparing a pharmaceutical composition of regadenoson with at least one

pharmaceutically acceptable carrier.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO ALLEGED INFRINGEMENT BY ACCORD

20. By a letter dated May 13, 2019, Accord notified Plaintiffs that Accord had submitted ANDA No. 213236 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("the Lexiscan Notice Letter").

RESPONSE: Admitted.

21. The Lexiscan Notice Letter states that Accord has submitted an ANDA under 21 U.S.C. § 355(j) to engage in the commercial manufacture, use, importation, offer for sale, or sale of the Accord ANDA product before the expiration of the '183 and '301 patents. Upon information and belief, Accord intends to—directly or indirectly—engage in the commercial manufacture, use, and sale of the Accord ANDA product.

RESPONSE: Admitted.

22. By filing ANDA No. 213236, Accord has necessarily represented to the FDA that the Accord ANDA product has the same active ingredient as Lexiscan, has the same dosage form and strength as Lexiscan, and is bioequivalent to Lexiscan.

RESPONSE: Accord admits that its ANDA seeks approval of a bioequivalent to Lexiscan that utilizes regadenoson as its active but denies that the regadenoson utilized in Accord's ANDA product is the form of the compound claimed in the patents in suit. Accord admits its ANDA product is in the same dosage form as Lexiscan. Accord denies all remaining allegations. Allegations not expressly admitted are denied.

23. Upon information and belief, Accord is seeking approval to market the Accord ANDA product for the same approved indication as Lexiscan.

RESPONSE: Admitted.

24. In the Lexiscan Notice Letter, Accord stated that the '183 and '301 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Accord ANDA product.

RESPONSE: Admitted.

25. In the Lexiscan Notice Letter, Accord offered confidential access to portions of its ANDA No. 213236, on terms and conditions set forth in the Lexiscan Notice Letter ("the Accord Offer"). Accord requested that Plaintiffs accept the Accord Offer before receiving access to Accord's ANDA No. 213236. The Accord Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Accord Offer contained a broad patent prosecution bar, which, among other things, does not have a carve out for *inter partes* reviews, and a broad bar on any work related to actions before the FDA. The Accord Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts. The restrictions Accord has placed on access to ANDA No. 213236 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

RESPONSE: Denied. Accord further objects to this paragraph as asserting allegations that are not relevant to the patents in suit or claims asserted and avers that the allegations have been asserted in bad faith.

26. Upon information and belief, Accord uses processes covered by the claims of the '883 patent to prepare Accord's ANDA product.

RESPONSE: Denied. Accord avers this allegation has been set forth in bad faith.

27. Upon information and belief, the product resulting from the process claimed in the '883 patent is made, used, offered for sale, and/or sold without material change to the product resulting from the process claimed by the '883 patent.

RESPONSE: Denied. Accord avers this allegation has been set forth in bad faith.

28. The product resulting from the process claimed by the '883 patent is not a nonessential and/or trivial component of another product.

RESPONSE: Accord is without information sufficient to form a belief as to the truth of the allegations and denies them on that basis.

29. Upon information and belief, Accord intends to import into the United States and/or offer to sell, sell, make, and/or use within the United States the Accord ANDA product, which is made by the process patented by the '883 patent, prior to the expiration of the '883 patent.

RESPONSE: Denied.

30. Upon information and belief, Accord has made and will continue to make substantial and meaningful preparations to practice the method claimed in the '883 patent and/or import, offer to sell, sell, make, and/or use within the United States its ANDA product, which is made by the process covered by the '883 patent, prior to the expiration of the '883 patent. Accord's preparations include, but are not limited to, developing Accord's generic product and filing ANDA No. 213236.

RESPONSE: Denied.

31. Upon information and belief, Accord plans to continue to use the processes claimed in the '883 patent to make its ANDA product.

RESPONSE: Denied.

32. Upon information and belief, Accord had actual and/or constructive notice of the '883 patent prior to filing ANDA No. 213236.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT I (ALLEGED INFRINGEMENT OF THE '183 PATENT)

33. Each of the preceding paragraphs 1 to 32 paragraphs is incorporated as if fully set forth herein.

RESPONSE: Accord incorporates its responses to paragraphs 1 to 32 as if fully set forth herein.

34. Accord's submission of ANDA No. 213236 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Accord ANDA product prior to the expiration of the '183 patent constituted a technical act of infringement of at least one of the claims of the

'183 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1-3 and 8-9, under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

35. Accord's commercial manufacture, use, offer to sell, sale, or importation of the Accord ANDA product prior to the expiration of the '183 patent, and its inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '183 patent, either literally or under the doctrine of equivalents, including at least claims 1-3 and 8-9, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g).

RESPONSE: Denied.

36. Upon FDA approval of Accord's ANDA No. 213236, Accord will infringe one or more claims of the '183 patent, either literally or under the doctrine of equivalents, including at least claims 1-3 and 8-9, by making, using, offering to sell, and selling the Accord ANDA product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '183 patent by others, under 35 U.S.C. § 271(a), (b), (c) and/or (g), unless enjoined by the Court.

RESPONSE: Denied.

37. If Accord's marketing and sale of the Accord ANDA product prior to expiration of the '183 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT II (ALLEGED INFRINGEMENT OF THE '301 PATENT)

38. Each of the preceding paragraphs 1 to 37 is incorporated as if fully set forth herein.

RESPONSE: Accord incorporates its responses to each of preceding paragraphs 1 to 37 as if fully set forth herein.

39. Accord's submission of ANDA No. 213236 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Accord ANDA product prior to the expiration of the '301 patent constituted a technical act of infringement of at least one of the claims of the '301 patent, either literally or under the doctrine of equivalents,

including but not limited to claims 6, 11, and 17, under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

40. Accord's commercial manufacture, use, offer to sell, sale, or importation of the Accord ANDA product prior to the expiration of the '301 patent, and its inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '301 patent, either literally or under the doctrine of equivalents, including but not limited to claims 6, 11, and 17, under 35 U.S.C. § 271(a), (b), (c) and/or (g).

RESPONSE: Denied.

41. Upon FDA approval of Accord's ANDA No. 213236, Accord will infringe one or more claims of the '301 patent, either literally or under the doctrine of equivalents, including but not limited to claims 6, 11, and 17, by making, using, offering to sell, and selling the Accord ANDA product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '301 patent by others, under 35 U.S.C. § 271(a), (b), (c) and/or (g), unless enjoined by the Court.

RESPONSE: Denied.

42. If Accord's marketing and sale of the Accord ANDA product prior to expiration of the '301 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT III (DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '883 PATENT)

43. Each of the preceding paragraphs 1 to 42 is incorporated as if fully set forth herein.

RESPONSE: Accord incorporates its responses to each of paragraphs 1 to 42 as if fully set forth herein.

44. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exist between Plaintiffs and Accord regarding infringement of the '883 patent.

RESPONSE: Denied.

45. Accord has made and will continue to make substantial and meaningful preparations to perform the processes claimed in the '883 patent or to import a product which is made by a process claimed by the '883 patent into the United States prior to the expiration of the '883 patent.

RESPONSE: Denied.

46. Accord's conduct including, but not limited to, the filing of ANDA No. 213236 and attempting to meet the regulatory requirements for approval of ANDA No. 213236, demonstrate a refusal to change its course of action.

RESPONSE: Denied.

47. Accord's performance of the processes claimed in the '883 patent and/or importation in the United States, offers to sell, sale, and/or use of Accord's products made by the patented process prior to the expiration of the '883 patent, and its inducement of and/or contribution to such conduct, would infringe claims 1-5, of the '883 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c) and/or (g).

RESPONSE: Denied.

48. Plaintiffs should be granted a judicial declaration that the claims of the '883 patent are not invalid, are not unenforceable and that the importation into the United States, use, offer for sale, and/or sale in the United States of a product made using the processes claimed in the '883 patent, the use of the processes claimed in the '883 patent, and/or actively inducing and contributing to infringement of the '883 patent by others will constitute infringement of the '883 patent under 35 U.S.C. § 271(a), (b), (c) and/or (g).

RESPONSE: Denied.

49. If Accord's marketing and sale of the Accord ANDA product prior to expiration of the '883 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

Any allegation in Plaintiffs' Complaint not expressly admitted by Accord is denied. Having answered Plaintiffs' Complaint, Accord denies Plaintiffs are entitled to any of the relief requested in the Complaint or to any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Accord asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiffs.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, importation or the product that is the subject of Accord's ANDA has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patents-in-suit.

SECOND SEPARATE DEFENSE

One or more claims of the patents in suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or for satisfying other bases (including judicially-created bases) for invalidation or unenforceability.

THIRD SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office leading to the patents-in-suit, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the patents-in-suit is infringed by the product that is the subject of Accord's ANDA.

FOURTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

FIFTH SEPARATE DEFENSE

Any and all additional defenses discovery may reveal.

WHEREFORE, Accord hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: July 16, 2019

/s/ Kenneth L. Dorsney

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